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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,850	12/14/2001	Patrick M. Hughes	D-3004	7435

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EXAMINER	
FAY, ZOHREH A	

ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
12/02/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/016,850	HUGHES ET AL.	
	Examiner	Art Unit	
	ZOHREH A. FAY	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12,14-16 and 24-26* is/are pending in the application.

4a) Of the above claim(s) *10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9, 11-12, 14-16 and 24-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 1-12, 14-16 and 24-26 are presented for examination.

Claims 10 is withdrawn from consideration.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 7, 9 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 01/92288.

WO Patent teaches contains a central vitamin core, which is an ophthamologically useful therapeutic compound. Therefore, all is necessary to arrive at the claimed subject matter is to select a compound having the bridged structure recited in claim 1. And, since adamantine and flumadine are named by the WO 01/92288 at the top of page 92, vitamin B conjugates of those compounds are anticipated by the prior art

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6, 7, 8, 9, 11-12, 14-16 and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Desantis, JR. (US 2001/0047012) and Collins et al. (WO 01/92288).

Desantis teaches a combination therapy for treating glaucoma using a glutamate antagonist and an intraocular pressure-lowering compound. Brimonidine is taught as the preferred intraocular pressure-lowering compound, and memantine is considered a glutamate antagonist being added to brimonidine. See claims 1-7. Collins teaches various pharmaceutical conjugates comprising a bioactive agent that is covalently

bound directly or indirectly to a linker. Efficacy enhancing components of formula A are disclosed on page 92. Therefore, in view of the combined teachings of Desantis and Collins, one skilled in the art of formulation chemistry who seeks a pharmaceutical conjugate comprising a therapeutic component and an efficacy enhancing component of instant formula A would have been motivated to prepare a formulation comprising two known therapeutically effective ophthalmic agents in a formulation that is conjugate to treat ocular pathologies. Such would have been obvious in the absence of evidence to the contrary, because memantine is established in the prior art as useful agent for conjugation with poorly soluble drugs. Such conjugates provide chemical stability and are known to dissociate under physiological conditions. The intended uses, as defined in claim 1 as "a therapeutic component" and "an efficacy enhancing component" confer no patentable weight to the composition claims. The applied references teach the combination of a compound of instant formula A with various therapeutic agents. The specification fails to define a "conjugate" as anything more than the combination of compounds wherein increased solubility or bioavailability is sought.

Applicant's arguments and remarks have been carefully considered, but are not deemed to be persuasive. Applicant alleges criticality to the differences in function of the claimed combination and the combination of the prior art. Appellant is reminded that the claims of the instant application are composition claims, therefore the intended use confer no patentable weight to the composition claims. Applicant's declaration has been carefully considered, but is not deemed to be persuasive. Applicant appears to have discovered another advantage of an old composition, which is being delivered to

the posterior segment of the eye in an amount of several folds that delivered to the anterior segment of the eye. Applicant's attention is drawn to In re Best and In re Fitzgerald. It is noted that In re Best (195 USPQ 430) and In re Fitzgerald (250 USPO 594) discuss support of rejection wherein the prior art discloses subject matter, which there is reason to believe inherently includes function that are newly cited or is identical to product instantly claimed. In such situation the burden is shifted to the applicant to " prove that subject matter to be shown in the prior art does not posses the characteristic relied on " (205 USPQ 594, second column, first full paragraph). There is no requirement that a person of ordinary skilled in the art would have recognized the inherent disclosure at the time invention, but only that the subject matter in fact is inherent in the prior art reference. Schering Corp v. Geneva Pharm. Inc., 339 F. 3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003); see also Toro Co v. Deere & Co., 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (fed. Cir. 2004). In the instant case applicant is using the same composition as prior art by applying it to the eye, therefore it is expected that such composition would inherently act the same as the composition of the instant application.

In conclusion, Desantis teaches a combination of brimonidine and memantine (elected species by appellant) in an ophthalmic formulation for the treatment of glaucoma. Collins et al. teach pharmaceutical conjugates with ophthalmic application. Efficacy enhancing components of Formula A are disclosed on page 92. The applied references teach the combination of compounds of formula A, such as memantine in combination with therapeutic agents such as brimonidine. The specification fails to

define a "conjugate" as anything more than the combination of compounds wherein the increased solubility or bioavailability is sought.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ZOHREH A. FAY whose telephone number is (571)272-0573. The examiner can normally be reached on Monday to Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fredrick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ZF
/Zohreh A Fay/
Primary Examiner, Art Unit 1612